Journal of the American College of Cardiology Vol. 54, No. 10, 2009

ISSN 0735-1097/09/$36.00

CORRESPONDENCE

Research Correspondence

Safety and Efficacy of Pacemaker Reuse in Underdeveloped Nations

A Case Series

To the Editor: The morbidity and mortality associated with cardiovascular disease (CVD) has been steadily declining in industrialized nations over recent decades due to innovations in technology and widespread access to health care; however, the prevalence of CVD is expected to increase 137% between 1990 and 2020 for those living in low- and middle-income countries (LMIC). The increasing prevalence as well as a lack of financial means to address the associated morbidity will result in further disparities between developed nations and LMIC (1). The gap in medical treatment is clearly evident in the field of cardiac electrophysiology—specifically in device implantation. This study examines the safety and efficacy of post-mortem pacemaker donation from the U.S. to patients in LMIC.

From January 2008 to July 2008, a total of 50 pacemakers were donated from Detroit metropolitan area funeral homes to World Medical Relief—a nonprofit charitable organization specializing in delivery of medical equipment to LMIC. Of these devices, 18 (36%) were found to have battery life ≥70%. One of the devices was excluded due to visual defects in structural integrity of the lead terminals.

Informed consent was obtained from all patients' families in order to remove and donate the pacemakers post-mortem. Trained physicians at World Medical Relief inspected and interrogated all pacemakers to assess functionality and remove all patient identifiers. Only pacemakers with ≥70% battery life were incorporated into the study. Devices from patients with evidence of communicable infectious disease or that were previously recalled were not accepted.

Devices included in the study were then prepared for sterilization. Pipe cleaners and other instruments were employed to ensure that all debris was removed, specifically at the lead insertion sites. Devices were then bathed with isopropyl alcohol and soaked overnight in Asepti-zyme (Ecolab, St. Paul, Minnesota) at a concentration of 1:128. Pacemakers were wiped with 70% ethanol, air dried, packed in gas permeable envelopes, and decontaminated via an 8-h ethylene oxide gas sterilization protocol.

Twelve patients were selected for pacemaker implantation at the University of Philippines-Philippine General Hospital utilizing guidelines for standard of care during the period of September 2008 to December 2008. All patients underwent a detailed socioeconomic evaluation and were deemed financially incapable of procuring a permanent pacemaker.

Of the refurbished devices, 8 were implanted as single-chamber devices while the remaining 4 were implanted as dual-chamber devices. For all devices, new leads were purchased through third-party vendors.

The average age of recipients of refurbished pacemakers was 62 ± 10 years (range 28 to 82 years), with 50% of recipients being men. Eleven patients received their initial pacemaker while 1 patient was undergoing elective replacement due to battery end of life. Indications for pacemaker placement included complete heart block (n = 10) and sick sinus syndrome (n = 2). Three patients required transvenous pacing before device placement (Table 1).

There were no complications in the patients with refurbished pacemakers. All patients presented for follow-up at 1 week and 2 months post-procedure. There were no deaths during this follow-up period. Six patients continue to be monitored at the University of Philippines-Philippine General Hospital, while 6 patients have been referred to their primary cardiologists for follow-up and monitoring.

In this study, we examined the feasibility and safety of post-mortem pacemaker donation for underserved nations. In our cohort of 12 patients, all refurbished devices were functioning appropriately within 2 months of implantation. Moreover, none of the patients experienced procedural complications such as device malfunction or pacemaker infection despite the fact that several patients were higher risk due to temporary pacing before permanent device implantation. We believe that post-mortem pacemaker implantation is a safe and effective method of delivering health care to those in underserved countries such as the Philippines.

Urbanization, globalization, and increasing age have culminated in an epidemiological evolution of CVD as the primary cause of death globally (2). Moreover, of the 17.5 million deaths worldwide attributed to CVD in 2005, 80% occurred in LMIC (3). Many of these countries lack the financial resources to address this epidemic of CVD. As a result, resources are often directed away from high-cost treatment strategies such as implantable cardiac rhythm management devices.

The argument for pacemaker reuse has been debated for decades within national health care systems. Although the reuse of explanted pacemakers in the U.S. is restricted by the Food and Drug Administration, countries such as Canada and Sweden have published reports highlighting the clinical safety and efficacy of reimplantation (4–6). The 2002 American College of Cardiology/American Heart Association/North American Society of Pacing and Electrophysiology Guideline Update for Implantation of Cardiac Pacemakers even acknowledges that pacemaker reuse "may eventually add significantly to the cost-effectiveness of cardiac pacing" (7).

In light of the widening health care disparity seen between the industrialized world and developing nations, we feel that pacemaker reuse is an ethical obligation to address the medical needs for those who could not afford therapy otherwise. In accordance with previous studies, our data re-emphasizes that post-mortem pacemaker donation is a safe and effective method of alleviating the morbidity associated with CVD in many individuals. Ongoing research is necessary to evaluate the feasibility of regional and potentially nationwide pacemaker donation programs in order to further alleviate the morbidity and mortality of symptomatic bradyarrhythmia seen in underprivileged nations.

Table 1 Clinical Characteristics of Patients Receiving Refurbished Pacemakers

Patient #	Age (Yrs)	Sex	Pacemaker Indication	Clinical Symptoms	Device Manufacturer	Single Versus Dual Chamber	Complications	Notable Events
1	68	M	Sick sinus syndrome	Syncope	Medtronic	Single	None	—
2	74	M	Third-degree block	Dyspnea	St. Jude Medical	Dual	None	—
3	70	M	Sick sinus syndrome	Pre-syncope	Biotronik	Dual	None	—
4	28	F	Third-degree block	Syncope	Medtronic	Single	None	—
5	76	F	Third-degree block	Syncope	Medtronic	Single	None	*†
6	47	F	Third-degree block	Syncope	Medtronic	Single	None	‡
7	65	F	Third-degree block	Syncope	St. Jude Medical	Single	None	*§
8	55	M	Third-degree block	Syncope	St. Jude Medical	Single	None	†
9	60	F	Third-degree block	Syncope	St. Jude Medical	Dual	None	—
10	61	M	Third-degree block	Syncope	St. Jude Medical	Dual	None	—
11	55	F	Third-degree block	Syncope	St. Jude Medical	Single	None	†
12	82	F	Third-degree block	Syncope	Biotronik	Single	None	*

*Required transvenous pacing before device placement; †patient had syncopal episodes for 1 year before device placement; ‡device was placed due to end of battery life on previous pacemaker; §patient remained in hospital for 15 days with transvenous pacemaker while waiting for procurement of device.

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doi:10.1016/j.jacc.2009.04.096

Please note: The authors would like to acknowledge and thank the Hewlett Foundation and Mardigian Foundation for their support of this project. Dr. Tangco has served on the Speakers' Bureau for and has received honoraria for lectures given for Pfizer Philippines, AstraZeneca Philippines, UNILAB, Inc., and Getz Pharma Philippines. Dr. Oral is a founder and equity owner of Ablation Frontiers, Inc.; has served as a consultant to Ablation Frontiers; and has received research grants from St. Jude Medical, Inc. and Boston Scientific.

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Key Words: pacemaker reuse ■ health care disparity ■ low- and middle-income countries.

Letters to the Editor

The Right Ventricular Outflow Tract in Arrhythmogenic Right Ventricular Cardiomyopathy

Dalal et al. (1) describe the accordion sign in family members of arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C) probands as a promising tool for the early diagnosis of the disease. Besides this qualitative feature, which also was seen in the right ventricular outflow tract (RVOT)/subtricuspid region, they also mention that quantitative right ventricular parameters tended to be abnormal in those with ≥1 criteria point in their reclassified approach. However, they do not mention whether the RVOT was enlarged in this cohort, a fact we find surprising because in a previous study (2) from the same group, 66% of patients with ARVD/C had an enlarged RVOT measured on standard axial images.

Given the fact that Corrado et al. (3) have suggested that an early/minor form of ARVD/C may primarily involve the RVOT, mimicking idiopathic RVOT tachycardia, we believe that quantitative assessment of the RVOT should always be part of the